

### REMARKS

This is in response to the Office Action that was mailed on August 17, 2006. Claims 1, 6, 12, and 13 are rewritten to emphasize the long-term inhibition of degradation feature of the present invention. New claims 21-24 correspond to former claims 17/1, 18/6, 19/12, and 20/13, rewritten in independent form and modified in view of disclosure throughout the specification. New claims 21-24 also specify that a face of the container coming into contact with the specimen is coated with silicone. Claims 17-20 are accordingly cancelled, without prejudice. No new matter is introduced by this Amendment. Claims 1, 3, 6, 12-16, and 21-24 are pending in the application. Favorable action on the merits of all of the claims herein is earnestly solicited.

Claims 1, 3, 6, and 12-20 were rejected under 35 U.S.C. §102(b) as being anticipated by Davidson *et al.*, *Circulation*, Vol. 91, No. 4, pages 1276-1277 (1995). The rejection is not applicable to the claims in their present form.

Davidson collects blood samples that include brain natriuretic peptide in *polypropylene* tubes containing EDTA, some of which do not contain aprotinin. Davidson teaches that “a blood sample taken into a standard EDTA tube and transported to the laboratory for separation *within 6 hours* will provide an accurate measurement of plasma ... BNP concentrations”. Emphasis supplied. Applicants do not believe that the results reported by Davidson are predictive of the present invention. Davidson teaches that the inter-assay coefficient of variability for BNP samples in testing up to 6 hours was 14.8%. This would appear to be consistent with a decrease in residual BNP immunoreactivity over 6 hours of 14.8%. Arithmetically, the decrease in residual BNP immunoreactivity over 24 hours would be 59.2%. As a practical matter, decrease in residual BNP immunoreactivity would probably accelerate geometrically and be much more than 59.2%. In any case, nothing in the Davidson reference teaches or suggests the step of “permitting the specimen to stand in the container for at least 24 hours at 25°C”.

To amplify on the above discussion, Davidson discloses the stability of N-ANP and BNP in whole blood in polypropylene tubes after standing for up to 6 hours at room temperature. Davidson refers to the blood samples being “transported to the laboratory for separation within 6 hours”. Persons of ordinary skill in the art considering the Davidson disclosure would not be

motivated to attempt to maintain blood for longer than 6 hours in polypropylene tubes. However, as a practical matter, it often takes longer than 6 hours – sometime more than 2 days – after a blood or plasma sample is collected from a patient before the sample can be subjected to diagnostic procedures. The present invention teaches that the activities of natriuretic peptides can remain at a level of 50% or more even after 24-72 hours. See Applicants' Figure 2.

With respect to claims 21-24, nothing in Davidson teaches or suggests “collecting [a] specimen containing brain natriuretic peptide into a container, wherein a face of the container coming into contact with the specimen is coated with silicone”.

Accordingly, Davidson neither anticipates nor renders obvious the methods of present claims 1, 3, 6, 12-16, and 21-24.

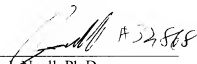
Applicants respectfully request that the Examiner withdraw the outstanding rejection, and issue a Notice of Allowance.

If there are any questions concerning the present application, the Examiner is respectfully requested to contact Richard Gallagher (Reg. No. 28,781) at (703) 205-8008.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Dated: November 17, 2006

Respectfully submitted,

By  #32868  
Mark J. Nuell, Ph.D.  
Registration No.: 36,623  
BIRCH, STEWART, KOLASCH & BIRCH, LLP  
8110 Gatehouse Rd  
Falls Church, Virginia 22040-0747  
(703) 205-8000  
Attorney for Applicant